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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASTRA AKTIEBOLAG, *et al.*, Plaintiffs,	99-CIV-8926 (DLC) 99-CIV-9887 (DLC)
v.	
ANDRX PHARMACEUTICALS, INC., Defendant.	
In re OMEPRAZOLE PATENT LITIGATION	M-21-81 (DLC) MDL Docket No. 1291

ASTRA AKTIEBOLAG'S OPPOSITION TO ANDRX PHARMACEUTICAL'S MOTION FOR SUMMARY JUDGMENT ON DAMAGES

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Plaintiffs ("Astra") respectfully submit this memorandum in opposition to Defendant's ("Andrx") motion for summary judgment on damages.

INTRODUCTION

Andrx commercially manufactured at least $650 million of infringing product – product that Andrx concedes for the purpose of this motion was made outside the "safe harbor" provisions of the Hatch-Waxman Act. The remaining portion of the case addresses the damages and other monetary relief owed to Astra for Andrx's infringement.

The Court has already decided, with regards to Astra's entitlement to damages for Andrx's conduct, that "manufacture alone suffices" even in the absence of sales. (Ex. 1,[1] Opinion & Order, Dkt.[2] 35, p. 15). The Court's consideration and decision on this issue, as well as Andrx's previously presented final judgment/res judicata argument (recast by Andrx as "double recovery"), is law of the case. The Court has already rejected each issue raised in Andrx's motion and should not revisit them now. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 815-16 (1988); *Agostini v. Felton*, 521 U.S. 203, 236 (1997).

Even if considered, Andrx's positions are meritless. Andrx's statutory construction arguments fail to apply the most basic rules of construction. For example, when addressing the meaning of "commercial manufacture" in 35 U.S.C. § 271(e)(Ex. 2), Andrx failed to consider the words in the statute itself to determine whether the language was clear and unambiguous. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Instead, Andrx assumed ambiguity and went on to contort the statutory language "commercial manufacture, use, offer to sell, or sale" to mean the same as the clearly different term "commercial marketing." The commercial marketing definition selected by Andrx has nothing to do with the statutory language

[1] "Ex. _" refers to the exhibits attached to the Declaration of Suraj K. Balusu in Support of Astra Aktiebolag's Opposition to Andrx Pharmaceutical's Motion for Summary Judgment on Damages, filed concurrently herewith.
[2] Unless otherwise indicated, docket entries refer to *Astra Aktiebolag v. Andrx Pharm. Inc.*, Case No. 99-cv-9887.

at issue; it is from a regulation addressing a different and unrelated portion of the statute. Moreover, Andrx also fails to explain why two different phrases in the same statute ("commercial marketing" and "commercial manufacture) should have the same meaning. *United States v. Mason*, 692 F.3d 178, 182-83 (2d Cir. 2012).

Simply put, Astra and the Court should not have been made to address the issues in Andrx's motion. The motion should be denied under the doctrine of law of the case, and because it is based on a fatally flawed statutory construction.

FACTUAL BACKGROUND

The factual background is addressed in the February 2, 2010 Opinion and Order and is incorporated herein by reference. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 2-5).

I. ANDRX'S MANUFACTURE OF THE ANDA PRODUCT AT ISSUE FALLS OUTSIDE THE STATUTORY SAFE HARBOR PROVISION

For the purposes of this motion, Andrx admits that the manufacture of product that is the subject of Astra's damages claims are not exempt under the safe harbor provision, 35 U.S.C. § 271(e)(1). (Andrx's Opening Brief,[3] Dkt. 83, p. 12, n. 6).

Andrx manufactured large quantities of the infringing omeprazole product for a commercial purpose – to sell it. In the fall of 2001, Andrx began large scale commercial manufacture of its generic omeprazole product to build inventory, stockpiling commercial quantities to maximize the profits of its anticipated sales. (Andrx's Statement of Undisputed Facts[4], Dkt. 82, ¶ 22; Ex. 3, Transcript of Investors Conference Call on October 31, 2002, p. 9). Andrx manufactured this product ***after*** receiving FDA approval.

[3] Andrx Pharmaceuticals, Inc.'s Memorandum of Law in Support of its Motion for Summary Judgment on Damages ("Andrx's Opening Brief"), Dkt. 83, dated March 8, 2013.
[4] Andrx Pharmaceuticals, Inc.'s Statement of Undisputed Facts in Support of its Motion for Summary Judgment on Damages ("Andrx's Statement of Undisputed Facts"), Dkt. 82, dated March 8, 2013.

During a 2002 investors' conference call to announce its third quarter financial results and explain the disposition of the infringing Andrx omeprazole product, Andrx's Chief Financial Officer represented that the Company's profits were adversely affected by a "$41 million charge to full reserve for generic Prilosec as a result of an unfavorable court decision." (Ex. 3, Transcript of Investors Conference Call on October 31, 2002, p. 3).

Andrx's Chief Financial Officer also represented that the production would have generated significant revenue for the Company:

> As you know, and we've disclosed, we have produced ***$41 million at cost of generic Prilosec*** and we currently still have approximately ***$23 million at cost of inventories*** that have yet to be launched. So that $64 million of cost if you assume a 90% selling margin on those I mean that implies ***$650 million of net sales***[. A]t 80% selling margins that implies $320 million. [*sic*]

(Id. at 9) (emphasis added).

In its 2002 10-K report, Andrx represented that it was facing liability for its decision to build inventory:

> Astra has also advised the District Court that it believes it may be entitled to damages as a result of Andrx's decision to build an inventory of its product prior to the court's determination.

(Ex. 4, ANDRX CORP /DE/ - ADRX 2002 Form 10-K, filed March 31, 2003, p. 26).

These facts show that the product manufactured that is the subject of Astra's damages claim was large scale manufacture for commercial purposes, and constitutes "commercial manufacture" of patented products compensable with damages under 35 U.S.C. § 271(e)(4)(C).

These facts also show that Andrx knew and understood as early as 2002 that it would face a damages claim as a result of commercial stockpiling for the 650 million dollars in ANDA product that Astra has proven to exist based on the above Andrx admissions.

While Andrx's motion is premised on the alleged absence of infringing "sales," Andrx fails to address whether any of the product was "offered for sale" or "used" prior to its final disposition. Andrx's only support is a single conclusory sentence that "[b]ased on my review of Andrx's records, ***I believe*** that Andrx never sold any of the capsules that are the subject of Astra's 'commercial manufacture' claim." (Dkt. 28, Decl. of Michael Bryner at ¶¶ 1, 7 (Dec. 2, 2008)). The declarant, Mr. Bryner, has no personal knowledge and did not indicate which documents he relied on to determine the absence of sale, or address other infringing activity such as "use" or "offers for sale." This failure alone is enough to warrant denial of Andrx's motion.

II. THE "LAW OF THE CASE" DOCTRINE APPLIES TO THE ISSUES PREVIOUSLY ADDRESSED BY THE PARTIES AND THE COURT

The Court's February 2, 2010 Opinion and Order addresses the same issues now being raised in Andrx's summary judgment motion. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35).

In the February 2, 2010 Opinion and Order, the Court rejected Andrx's argument that "supplementation [of the Complaint] would be futile because Andrx never sold its omeprazole formulation and therefore Astra was never injured and can claim no royalties." (Id. at 15). The Court analyzed 35 U.S.C. § 271(e) and all arguments presented by Andrx before deciding that "[t]he statute clearly provides that damages may be awarded for an act of infringement if there has been 'commercial manufacture, use, offer to sell, or sale,' 35 U.S.C. § 271(e)(4)." (Id. (emphasis in original)).

To reach this ruling, the Court considered the three references to "commercial manufacture" in 35 U.S.C. § 271(e):

- The Court examined § 271(e)(2) which identifies the acts that are considered infringement: "…it shall be an act of infringement … if the purpose of such [ANDA] submission is to obtain approval … to engage in the ***commercial manufacture***, use or

sale of a drug …." (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 10-11 (emphasis added)).

- The Court examined § 271(e)(4) which addresses the permissible remedies under the statute, namely "injunctive relief … to prevent the commercial manufacture, use, offer to sell, or sale …" and "damages or other monetary relief only if there has been commercial manufacture, use, offer to sell or sale …." (Ex. 1, Dkt. 35, pp. 10-11).
- The Court was also aware of the safe harbor provision, § 271(e)(1), pointing out that it is not "an act of infringement to make, use offer to sell or sell … a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates that manufacture, use or sale of drugs…." (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 14, n. 3).

In short, the Court considered whether damages were available for commercial manufacture by itself under § 271(e) absent sales, offers for sale or other uses, and determined that "commercial manufacture" without more was compensable. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 15-16). In its decision, the Court expressly considered case law presented by Andrx again in its present motion, including but not limited to *In re Apotex, Inc.*, 49 Fed. Appx. 902, 903 (Fed. Cir. Oct. 9, 2002), and *Ortho-McNeil Pharms., Inc. v. Mylan Labs., Inc.*, 267 F. Supp. 2d 545, 549 (N.D. W. Va. 2003). (Id.).

The Court also considered and rejected Andrx's argument that the final judgment entered in 2002 barred Astra's supplemental pleading under the doctrine of res judicata. (Id. at 7-9). As shown below, this fact is directly related to Andrx's "Double Recovery" theory. The Court held that since damages relief was not an issue at trial or one ready for resolution in October 2002, it is not precluded by the October 30, 2002 judgment. (Id. at 8-9).

The Court also rejected Andrx's argument relating to Astra's alleged delay, in its February 2, 2010 Opinion and Order. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 17-18). The selected facts presented by Andrx relating to delay in its summary judgment motion are repetitive of the facts already considered and rejected by the Court. Andrx did not rely on these facts in its current motion. In any event, the Court held that "Astra has not unduly delayed" and that "there is no evidence of bad faith by Astra or prejudice to Andrx." (Id. at 17-18). Astra reserves the right to address these facts should Andrx apply them to an argument in this motion.

Andrx filed a motion for reargument or reconsideration of the Court's February 2, 2010 decision. (Andrx's Reconsideration Motion,[5] Dkt. 37). While Andrx sought reconsideration of the res judicata/final judgment issue, it could have but did not raise other additional issues in the reconsideration. (Ex. 5, Andrx's Reconsideration Brief,[6] Dkt. 38, pp. 1-2). The Court found that it had not overlooked any controlling decision or other matters that might alter its decision, and denied Andrx's reconsideration motion. (Ex. 6, Order (April 5, 2010), Dkt. 40, p. 2).

LEGAL STANDARD

Summary judgment is not appropriate if there are disputed issues of material fact. Fed. R. Civ. P. 56(c); *Hunt v. Cromartie*, 526 U.S. 541, 549 (1999); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Stryker Corp. v. Davol Inc.*, 234 F.3d 1252, 1257 (Fed. Cir. 2000). It is the movant's burden to identify the basis for its motion and to demonstrate that no evidence supports plaintiff's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Arthur A. Collins Inc. v. Northern Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000). When a court considers summary judgment, all factual disputes, and all inferences, are resolved in favor of the non-

[5] Notice of Motion to Reargue or for Reconsideration of the Court's February 2, 2010 Decision ("Andrx's Reconsideration Motion"), Dkt. 37, dated Feb. 16, 2010.
[6] Defendant Andrx's Memo. of Law in Support of Andrx's Motion to Reargue or for Reconsideration of the Court's February 2, 2010 Decision ("Andrx's Reconsideration Brief"), Dkt. 38, dated Feb. 16, 2010.

moving party – here Astra. *United States v. Diebold*, 369 U.S. 654, 655 (1962); *Anderson*, 477 U.S. at 255; *DeMartini Sports Inc. v. Worth Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001).

ARGUMENT

I. THE COURT SHOULD NOT RE-VISIT ISSUES RAISED IN ANDRX'S SUMMARY JUDGMENT MOTION THAT WERE ALREADY DECIDED

A. The "Law of the Case" Doctrine

Under the "law of the case" doctrine, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Christianson*, 486 U.S. at 815-16 (quoting *Arizona v. California*, 460 U.S. 605, 618 (1983)); *see also* 1B James W. Moore, Jo D. Lucas & Thomas S. Currier, Moore's Federal Practice ¶ 0.404[1], at 117 (1991), *quoted in DiLaura v. Power Auth. of N. Y.*, 982 F.2d 73, 76 (2d Cir.1992) ("Under the doctrine of law of the case, a decision on an issue of law made at one stage of a case becomes a binding precedent to be followed in successive stages of the same litigation."). Thus, "a court should not reopen issues decided in earlier stages of the same litigation." *Agostini*, 521 U.S. at 236 (quoting *Messenger v. Anderson*, 225 U.S. 436, 444 (1912)). "'The purpose of [the law of the case] doctrine is to promote the judicial system's interest in finality and in efficient administration.'" *Lillbask ex rel. Mauclaire v. Sergi,* 193 F. Supp. 2d 503, 511 (D. Conn. 2002) (quoting *Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1982) (internal quotation marks omitted)).

Under the law of the case doctrine a court should not reconsider issues on summary judgment that were previously adjudicated. *See Nobel Ins. Co. v. City of New York*, 2006 WL 2848121 (S.D.N.Y. 2006) ("To the extent, however, that Judge Berman made legal conclusions which are not in any way altered by discovery, or by subsequent developments in the law, this Court will not here reconsider those prior rulings."); *In re Bogdanovich*, 301 B.R. 129 (Bankr.

S.D.N.Y. 2003) (denying summary judgment and stating "[t]here is nothing . . . that would provide a sufficient basis, consistent with the law of the case doctrine, for this Court to revisit Judge Garrity's denial of Mrs. Bogdanovich's motion to dismiss at this time"); *E.W. Kalkin, Inc. v. Fieldcrest Mills, Inc.*, 1985 WL 2252 (S.D.N.Y. 1985) ("Judge Sprizzo's denial of summary judgment remains valid law of the case. 'Where litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted to battle for it again.' . . . Accordingly, the motion for summary judgment is denied.") (quoting *Zdanok v. Glidden Company, Durkee Famous Foods Division*, 327 F.2d 944, 953 (2d Cir. 1964)); *Erie Conduit Corp. v. Metropolitan Asphalt Paving Ass'n*, 560 F. Supp. 305 (E.D.N.Y. 1983) ("Because virtually identical motions were denied by Judge Mishler prior to the transfer of the case to this Court, Judge Mishler's previous rulings stand as law of the case, and defendants' renewed motions [to dismiss and for summary judgment] must be denied.").

Andrx attempts to do just this, by rearguing issues in their motion for summary judgment that were previously decided by Judge Jones in connection with Astra's motion to supplement its complaint to include damages. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35). Specifically, in opposition to Astra's motion to supplement its complaint to include damages, Andrx argued (1) that amendment would be futile because Astra's supplemental complaint lacked merit;[7] and (2) the Court's final judgment barred Astra from supplementing its complaint. (Ex. 7, Andrx's Opp. to Motion to Supplement, Dkt. 29, pp. 15-16, 29-31). These arguments were rejected by the Court and should not be reopened. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 6); *Agostini*, 521 U.S. at 236 ("a court should not reopen issues decided in earlier stages of the same litigation."); *Christianson*, 486 U.S. at 815-16.

[7] Andrx argued that Astra's claims for damages must be able to survive summary judgment in order to be added. (Defendant Andrx's Memo. of Law in Opposition to Plaintiffs' Motion for Leave to File a Supplemental Complaint ("Andrx's Opp. to Motion to Supplement"), Dkt. 29, dated Dec. 2, 2008, pp. 2, 23).

B. The Court Previously Ruled that Damages Solely for the Manufacture of Generic Product are Available Under the Statute

Andrx's summary judgment motion reargues and seeks reconsideration of its previously rejected argument that Astra's damages claims are futile (and would not survive summary judgment) because Andrx never sold its infringing product.[8] In its 2008 briefing, Andrx alleged that Astra could not claim royalties where there were no sales, citing *In re Apotex, Inc.* and *Ortho-McNeil Pharms., Inc*. (Ex. 7, Andrx's Opp. to Motion to Supplement, Dkt. 29, pp. 30-31). The Court analyzed this issue and squarely rejected Andrx's argument. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 15-16). The Court emphasized that Andrx's analysis "misses the mark" as the "statute clearly provides that damages may be awarded for an act of infringement if there has been 'commercial manufacture, use, offer to sell or sale' 35 U.S.C. §271(e)(4)" and that "[c]ommercial manufacture alone suffices." (Id. (emphasis in original)). The Court decided that "the patent statute sets the minimum quantum of damages as no less 'than a reasonably royalty for the use made of the invention by the infringer.'" (Id. at 16 (quoting 35 U.S.C. § 284)).

Andrx admits that its present motion rehashes the same argument when noting that "Andrx briefly argued that there were 'no damages' because there were 'no sales'" in connection with their opposition to Astra's motion to supplement. (Andrx's Opening Brief, Dkt. 83, p. 16). Andrx, however, did not disclose that the Court dedicated almost 8 pages to Andrx's argument that Astra's claims were futile, including almost 2 pages addressing whether commercial manufacture without sale would succeed in a motion for summary judgment. The Court's

[8] Astra's second supplemental complaints allege damages and other monetary relief for Andrx's use, and offers to sell infringing omeprazole products in addition to manufacture. (Case No. 99-cv-8926, Ex. 8, Second Supplemental Complaint, Dkt. 138 & 134-1, dated Feb. 8, 2010, ¶ 18(i), ¶ 29(g); Ex. 9, Second Supplemental Complaint, Dkt. 36, dated Feb. 8, 2010, ¶ 19(i), ¶ 30(g)). Andrx's motion fails to allege an absence of infringing activity such as "use" and "offers for sale." And as explained above, its declarant never addresses these activities. This failure alone is enough to warrant denial of Andrx's motion.

consideration of this issue included analysis of the very same cases re-cited now (*In re Apotex, Inc.* and *Ortho-McNeil Pharms., Inc.*). (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 15).

Andrx cannot escape application of the "law of the case" doctrine by re-casting their arguments and alleging they are new. *Gould, Inc. v. United States*, 67 F.3d 925, 931, n. 5 (Fed. Cir. 1995) ("this appeal raises the same grounds for dismissal that we considered and rejected in *Gould II*. . . . To allow the government to make new arguments regarding the same grounds for relief would violate the purpose of the law of the case doctrine."); *Ransmeier v. Mariani*, 486 Fed. Appx. 890, 892-93 (2d Cir. 2012) (affirming the district court's application of the law of the case doctrine where the district court found there was no basis to reconsider its prior decision despite newly presented arguments); *see also Grocery Haulers, Inc. v. C & S Wholesale Grocers, Inc.*, 2013 U.S. Dist. LEXIS 12094, at *14 (S.D.N.Y. Jan. 28, 2013) ("Even if GHI's new arguments about C&S's putative waiver of its rights under the truth-in-billing statute were not foreclosed by the application of the law of the case doctrine…."). The law of the case doctrine "forecloses reconsideration of issues that were decided—***or that could have been decided***—during prior proceedings." *United States v. Williams*, 475 F.3d 468, 471 (2d Cir. 2007) (emphasis added). Andrx cannot avoid the consequences of failing to present its allegedly new arguments, based on old facts, when the Court previously decided the same issues.

C. The Court Previously Ruled that Final Judgment Does Not Bar Astra's Damages Claims

Andrx also re-alleges that the October 30, 2002 final judgment bars Astra's claims for damages. (Andrx's Opening Brief, Dkt. 83, pp. 17-19). Andrx has already argued this point twice before: first, in its opposition to Astra's motion to supplement its complaint, and then again in its motion for reargument or reconsideration. (Ex. 7, Andrx's Opp. to Motion to Supplement, Dkt. 29, pp. 15-17; Ex. 5, Andrx's Reconsideration Brief, Dkt. 38, pp. 2-7). The Court held that

"[d]amage relief was not an issue at trial or one ready for resolution in October 2002, and it is therefore not precluded by the October 30, 2002 judgment. While the judgment precludes the relitigation of infringement liability, it does not preclude the possibility of additional remedies for that infringement." (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 8-9). Then, in response to Andrx's motion for reargument or reconsideration, the Court found "that it has not overlooked any controlling decision or other matters that might alter its decision." (Ex. 6, Order (April 5, 2010), Dkt. 40, p. 2). Andrx's attempt to re-style these arguments as "Double Recovery" (Andrx's Opening Brief, Dkt. 83, p. 17-19) does not change the fact that it is simply rearguing the same previously ruled-on issue and is therefore barred by the law of the case doctrine.[9] *Gould, Inc.*, 67 F.3d at 931, n. 5.

All of the arguments put forth by Andrx in the present motion for summary judgment could have, and should have, been previously made when these same issues were briefed and decided by the Court. Under these circumstances, the "law of the case" doctrine governs. *United States v. Williams*, 475 F.3d 468, 471 (2d Cir. 2007). The Court should not allow Andrx to reopen these issues and should deny Andrx's motion for summary judgment.

II. ASTRA IS ENTITLED TO SEEK MONETARY RELIEF FOR ANDRX'S COMMERCIAL MANUFACTURE

A. The Plain Language Of The Statute Allows For Recovery Of Damages For "Commercial Manufacture"

If the Court is inclined to address issues already decided by this Court, and reconsider the issues raised in Andrx's summary judgment motion, the result will be the same – rejection of Andrx's arguments and motion.

[9] A narrow exception to this rule against "new arguments" – relitigation of an issue already decided may be justified where there is "an intervening change of law, significant new evidence, or the need to correct a clear error of law or manifest injustice." *United States v. Salerno*, 932 F.2d 117, 121 (2d Cir. 1991) – does not apply here. Andrx has not alleged, and cannot show, that this narrow exception applies here.

"[I]n interpreting a statute a court should always turn first to one, cardinal canon before all others . . . . [C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank*, 503 U.S. at 253-54. Indeed, "[w]hen the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'" *Id.* at 254 (quoting *Rubin v. United States*, 449 U.S. 424, 430 (1981)).

The statute is clear and unambiguous: "damages or other monetary relief may be awarded against an infringer only if there has been ***commercial manufacture***, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . ." 35 U.S.C. § 271(e)(4)(C) (emphasis added). The term "commercial manufacture" as used in the statute is unambiguous – manufacture outside the safe harbor provision that is addressed earlier in the same statute, namely 35 U.S.C. § 271(e)(1).

This is clear and evident when viewed within the context of the various subsections of 35 U.S.C. § 271(e):

- subsection (e)(1) carves out a narrow exception to infringement "solely for uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs;" (a "safe harbor" provision); and
- activities that fall outside of the subsection (e)(1) safe harbor provision ("commercial manufacture, use offer to sell or sale … or importation") may be enjoined ((e)(4)(C)) and damages or other monetary relief may be awarded ((e)(4)(D)).

Subsection (e)(1) addresses liability and expressly informs that it shall ***not*** be an act of infringement to ***make***, use, offer to sell, sell or import a patented invention for uses solely related to regulatory submissions (e.g. ANDA filings). 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make . . . solely for uses reasonably related to the development and submission

of information under a Federal law which regulates . . . drugs."). Subsection (e)(3) prohibits an injunction or other relief if the alleged infringer's activity falls within this safe harbor. 35 U.S.C. § 271(e)(3).

Subsection (e)(4) then describes the relief for acts of infringement that fall outside of the safe harbor of 35 U.S.C. § 271(e)(4)(C) ("damages or other monetary relief may be awarded . . . if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .").

The language "commercial manufacture" also appears in subsection (e)(2) ("It shall be an act of infringement to submit [an application] . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale . . . before the expiration of such patent"). 35 U.S.C. § 271(e)(2).

When read in context, the language "commercial manufacture . . ." refers to "making" that is outside the subsection (e)(1) safe harbor provision. As the words of the statute are clear, no further construction is necessary. *Connecticut Nat'l Bank*, 503 U.S. at 253-54.

Andrx concedes for the purpose of this motion that its manufacture and stockpiling are not exempt from liability under the safe harbor provision. (Andrx's Opening Brief, Dkt. 83, p. 12, n. 6). Therefore, the plain language of the statute provides for damages or other monetary relief to Astra, and Andrx's motion should be denied.

If the Court takes the next step, the legislative history for this portion of the statute does not convert the statutory language "commercial manufacturing" to the legislative history language "commercial marketing." Andrx made the same mistake when reviewing the legislative history that it made when reviewing the statute – namely, failing to review all portions addressing subsections (e)(1) through (e)(4) in context. When read in context, it is clear that the

legislative history refers to the acts of infringement in a shorthand manner and is not meant to change the acts identified in the statute.

For example, when addressing the safe harbor provision (subsection (e)(1)), the legislative history refers to "make, use or sell" but omits the statutory language "offer to sell" and "import." Ex. 10, H.R. Rep. No. 98-857, pt. 2, at 26 (Aug. 1, 1984), 1984 U.S.C.C.A.N. 2686, 2710. Also, the legislative history for subsection (e)(2) does not address the acts for which approval is being sought ("commercial manufacture, use or sale") even though those acts are expressly enumerated in subsection (e)(2) of the statute. Id.

The legislative history when summarizing §§ 271(e)(4)(B) and (C) uses the shorthand "commercial marketing" instead of the statutory language "commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States."

Statutory Language	Legislative History
(B) injunctive relief may be granted against an infringer to prevent the ***commercial manufacture, use, offer to sell, or sale within the United States or importation*** into the United States of an approved drug…, (C) damages or other monetary relief may be awarded against an infringer only if there has been ***commercial manufacture, use, offer to sell, or sale within the United States or importation*** into the United States of an approved drug…. 35 U.S.C. § 271(e)(4)(B) & (C).	Injunctive relief may be granted to prevent ***commercial marketing*** under an approved ANDA and monetary damages or monetary relief are authorized when ***commercial marketing*** has begun. Ex. 10, H.R. Rep. No. 98-857, pt. 2, at 27, 1984 U.S.C.C.A.N. 2686, 2711.

A fair reading of the legislative history does not lead to the conclusion that the use of the term "commercial marketing" was intended to narrow or change the meaning of the statutory language. Moreover, when the statutory language is different or broader than the legislative history language, the statutory language takes precedent. *Hall v. United States*, 132 S. Ct. 1882, 1884 (2012) ("the Court has cautioned against allowing ambiguous legislative history to muddy

clear statutory language.") (citing *Milner v. Dep't of Navy*, 131 S. Ct. 1259, 1266 (2011)); *Ardestani v. INS*, 502 U.S. 129, 135-36 (1991) ("The 'strong presumption' that the plain language of the statute expresses congressional intent is rebutted only in 'rare and exceptional circumstances,' *Rubin v. United States*, 449 U.S. 424, 430 (1981), when a contrary legislative intent is clearly expressed.") (citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432, n. 12 (1987); *Consumer Product Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980)). As explained above, "[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank*, 503 U.S. at 253-54.

B. Andrx Misconstrues The Meaning Of "Commercial Manufacture"

Andrx incorrectly construes the statutory language "commercial manufacture, use, offer to sell, or sale" to mean "commercial marketing." To reach this incorrect construction, Andrx relies on a regulation relating to another portion of the statute to construe "commercial marketing" to mean "introduction into interstate commerce for the purpose of sale." Andrx then argues that "commercial manufacture" in the statute wholly excludes all "manufacture" regardless of purpose. (Andrx's Opening Brief, Dkt. 83, pp. 9-10). Andrx's argument ignores the plain language of § 271(e)(4), misapplies a regulation relating to another portion of the statute, and fails to acknowledge that both phrases ("commercial manufacture" and "commercial marketing") appear in this other portion of the statute (highlighting that they have different meanings).

First, Andrx's approach disregards the "cardinal cannon" of statutory interpretation by ignoring the plain meaning of the statutory language. *Connecticut Nat'l Bank*, 503 U.S. at 253-54. By doing so, Andrx reads explicitly enumerated acts out of the statute, including manufacture, use, offer to sell and sale. The Court has already ruled that the plain language of the statute allows damages for each act of infringement, including each of these acts. (Ex. 1,

Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 15 ("The statute clearly provides that damages may be awarded for an act of infringement if there has been 'commercial manufacture, use, offer to sell, or sale, 35 U.S.C. § 271(e)(4)'") (emphasis in original)). Andrx's proposed meaning is directly at odds with the Court's prior ruling as well as the plain language of the statute.

Second, Andrx incorrectly urges that because the legislative history uses the phrase "commercial marketing" that the statute should be limited to commercial marketing. But as explained above, the plain language of the statute itself is not so limiting and it would be wrong as a matter of law to read the legislative history shorthand into the plain statutory language. *Hall*, 132 S. Ct. at 1884; *Milner*, 131 S. Ct. at 1266; *Ardestani*, 502 U.S. at 135-136.

Third, after grasping at the reference to "commercial marketing" in § 271(e)'s legislative history and then improperly reading that language into the statute, Andrx then erroneously relies on an unrelated regulation, issued more than 10 years after 271(e), to define that phrase. The regulation implemented an amendment to the Hatch-Waxman Act that addressed when a subsequent generic manufacturer could enter the market – an issue unrelated to patent infringement and remedies under § 271(e).[10]

The flaw in Andrx's approach is highlighted by two circumstances: (1) the language "commercial marketing" appears in the "other later amended statute," and (2) that later statute includes both statutory phrases "commercial marketing" and "commercial manufacture" showing that these phrases were used for different purposes and meant to have different meanings.

Regarding the first point, the statutory amendment expressly includes the phrase commercial marketing: "the application shall be made effective on the date that is 180 days after

[10] The Hatch-Waxman Act grants a 180-day exclusivity period for the first generic drug manufacturer to file an ANDA application if certain criteria are met. *See* 21 U.S.C. § 355(j). The amendment identifies "commercial marketing" as a triggering event to start counting the first generic filer's 180-day exclusivity period – after which the subsequent filer's ANDA may be approved.. 21 U.S.C. § 355(j)(5)(B)(iv)(I). The regulation Andrx cites defines the event to start counting that 180-day period. 21 C.F.R. § 314.107(c)(1).

the date of the first ***commercial marketing*** of the drug …by any first applicant." 21 U.S.C. § 355(j)(5)(B)(iv)(I) (emphasis added). The regulation relied on by Andrx was promulgated to clarify what the statutory language "commercial marketing" in the amendment meant. 21 C.F.R. § 314.107(c)(1). Simply put, the definition relied on by Andrx was meant to explain the statutory term "commercial marketing," not the statutory term "commercial manufacture."

As to the second point, Andrx's error is highlighted by the fact that just a few paragraphs above the phrase "commercial marketing" in the amended statute, the phrase "commercial manufacture" is expressly used: "if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the ***commercial manufacture*** or sale of the drug…." 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb)(IV). Both phrases, "commercial manufacture" and "commercial marketing," are in the same statute. As a matter of statutory construction, the two terms cannot have the same meaning. *United States v. Mason*, 692 F.3d at 178, 182-83 (2d Cir. 2012) ("'the use of different words within the same statutory context strongly suggests that different meanings were intended.'") (quoting *United States v. Maria*, 186 F.3d 65, 71 (2d Cir. 1999)); *SEC v. McCarthy*, 322 F. 3d 650, 656 (9th Cir. 2003) ("It is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words.") (citing *Russello v. United States*, 464 U.S. 16, 23 (1983); *Persinger v. Islamic Republic of Iran*, 729 F.2d 835, 843 (D.C. Cir. 1984); *Nat'l Insulation Transp. Comm. v. ICC*, 683 F.2d 533, 537 (D.C. Cir. 1982)).

Andrx's reliance on an unrelated regulation that defined a different statutory phrase than the one at issue is not reconcilable. Andrx's failure to address the presence of the statutory language "commercial marketing" in the statute related to the regulation or that the language at

issue in this case "commercial manufacture" was present in the statute raises concerns.[11] By giving the same meaning to two different phrases in the same statute, Andrx violates another basic cannon of statutory construction. *Id.*

C. Astra's Claim For Damages Is Consistent With The Hatch-Waxman Act's Policy And Purpose

Andrx's large scale manufacture is inconsistent with the express statutory language and purposes of the Hatch-Waxman Act. The Act created a limited infringement exception "***solely*** for uses reasonably related to the development and ***submission of information under a Federal law*** which regulates the manufacture, use, or sale of drugs or other veterinary biological products." 35 U.S.C. § 271(e)(1) (emphasis added). As noted above (and as conceded by Andrx for the purposes of this motion), Andrx's commercial manufacture was not solely for uses reasonably related to the development and submission of information under a Federal law and therefore was not protected by the safe harbor provision. (*See* Ex. 3, Transcript of Investors Conference Call on October 31, 2002, p. 9).

The Hatch-Waxman Act was enacted in part in response to *Roche Prods., Inc. v. Bolar Pharma. Co.*, 733 F.2d 858, 860 (Fed. Cir. 1984), which held that "the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements" constituted infringement. *Id.* at 861. The Hatch-Waxman Act legislative history notes that new subsection (e) to 35 U.S.C. § 271 has "the net effect of reversing the holding of the court in [*Roche*]." Ex. 10, H.R. Rep. No. 98-857, pt. 2, at 27, 1984 U.S.C.C.A.N. 2686, 2711-12. Accordingly, the policy and purpose behind § 271(e) was to remove as an act of infringement, the use of a patented drug for testing strictly related to FDA drug approval.

[11] Damages are available for more and potentially different activities than those that trigger the 180-day exclusivity period. Under 35 U.S.C. § 271(e), damages are available for commercial manufacture, use, offer to sell, sale or importation. The "commercial marketing" trigger is implicated only when there is "introduction or delivery for introduction into interstate commerce outside the control of the manufacturer…." 21 C.F.R. § 314.107(c)(4).

The legislative history emphasized the narrow nature of the safe harbor. Congress recognized that extending the § 271(e)(1) safe harbor too far would run afoul of the Constitution's "takings" clause ("taking" without just compensation in violation of the Fifth Amendment). *Id.* In addressing the "takings" concerns of the § 271(e), the legislative history indicates: "all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is de minimus." Ex. 10, H.R. Rep. No. 98-857, pt. 2, at 30, 1984 U.S.C.C.A.N. 2686, 2714. Andrx's proposed expansion of the § 271(e)(1) safe harbor to include stockpiling of infringing products, for commercial purposes and not for obtaining FDA approval, would not only be contrary to the policy underlying the act – it would also fly in the face of the U.S. Constitution's "takings clause," and completely disregard the carefully balanced approach to this issue taken by Congress.

Andrx's argument that the Act was designed to encourage "pre-commercial activity risk free" (Andrx's Opening Brief, Dkt. 83, p. 11) beyond those expressly permitted under the safe harbor provision is wholly unsupported. Extending the § 271(e)(1) safe harbor to cover manufacture and stockpiling of commercial batches of infringing product would be contrary to the policy and purpose of both the Patent Act and the Hatch-Waxman Act.

D. Astra's Request For Damages Is Not Contrary To The Weight Of History

Andrx's argument that this case is at odds with "the weight of history" was already considered and rejected by this Court. As addressed above in Section I(B), Andrx previously and unsuccessfully argued that Astra could not claim royalties where there were no sales, citing the same cases it relies on now. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 15 (citing *In*

re Apotex, Inc., 49 Fed. Appx. at 903 and *Ortho-McNeil Pharms., Inc.*, 267 F. Supp. 2d at 549).[12] The Court squarely rejected Andrx's argument after analyzing the cases cited by Andrx both then and now. As emphasized by the Court, the statute plainly allows for damages in the case of commercial manufacturing alone, without sales. (Ex. 1, Opinion (Feb. 2, 2010), Dkt. 35, p. 15).

Andrx cites no cases with facts similar to those before this Court. For example, Prilosec® was the largest selling drug in the world before Andrx's infringement, with sales over $6.2 billion in 2000 and over $5.6 billion in 2001. (AstraZeneca Annual Report and Form 20-F 2001, p.3, 34-35, (available at http://www.astrazeneca.com/Investors/Annual-reports (follow "2001" drop down to "Annual Report – English – Part one")); AstraZeneca Annual Report and Form 20-F 2000, p. 11, 38, (available at http://www.astrazeneca.com/Investors/Annual-reports (follow "2000" drop down to "Annual Report – English – Part one"))). Andrx commercially manufactured and stockpiled in violation of the Hatch-Waxman act to improperly extend the 180-day generic exclusivity period it would have been entitled to – a head start worth hundreds of millions of dollars to Andrx, and incredibly damaging to Astra. By stockpiling, and then flooding the market when its exclusivity period began, Andrx would have been able to increase its overall sales, cause a decrease in Astra's sales, and increase its market share before other

[12] Andrx also cites *Barr Labs*, *Novartis Corp*, and *Roche*. (Andrx's Opening Brief, Dkt. 83, p. 15). These cases are of no moment. First, as admitted by Andrx, the brand companies in these cases did not seek damages. (Id.). The fact that they did not seek damages does not mean that damages were unavailable. The first two opinions cited by Andrx were rulings on motions for preliminary injunctions. *Ortho McNeil Pharm., Inc. v. Barr Labs, Inc.*, No. 03-cv-4678, 2009 WL 2182665, at *1 (D.N.J. July 22, 2009); *Novartis Corp. v. Teva Pharm. USA, Inc.*, No. 04-4473, 2007 WL 1695689, at *2 (D.N.J. June 11, 2007). Damages would not and could not be sought at the preliminary injunction phase.

Andrx's reliance on *Roche* is also misplaced. The quote cited by Andrx from *Roche* is taken out of context: "Counsel for Roche was candid in explaining that he pushed so hard for the harsh [injunctive] relief he did because he thought any money damages [for the experimental use] would have to be nominal." (Andrx's Opening Brief, Dkt. 83, p. 15). In the following lines of the opinion, the Federal Circuit states "[t]he correctness of this belief has not been briefed or argued . . . but tentatively, at least, we are skeptical. It is clear that the economic injury to Roche is, or is threatened to be, substantial, even though the amount of material used in the tests was small." *Roche Prods., Inc.*, 733 F.2d at 866.

generic companies could enter the market. This is clearly not an exempt manufacture under the safe harbor or a situation where the damages for manufacture are nominal.[13]

There is no question that significant damages may be incurred for the manufacture without sale. As just one example, in the recent *Monsanto* case, a jury awarded Monsanto $1 billion in reasonable royalty damages for commercial development of Monsanto's patented genetically modified seed even though none of the patented product was sold. *Monsanto Co. v. E.I. Dupont De Nemours*, 4:09-cv-00686, (E.D.M.O. 2009), Dkt. 1650, p. 5; *Id.*, Dkt. 1534, pp. 29, 62. That case was reportedly settled for $1.75 billion. (Carey Gillam, *Monsanto, DuPont strike $1.75 billion licensing deal, end lawsuits*, REUTERS (online) (March 26, 2013), http://www.reuters.com/article/ 2013/03/26/us-monsanto-dupont-gmoid USBRE92P0IK20130326).

E. The Court Already Rejected Andrx's "Double Recovery" Argument

Astra's request for damages is not a double recovery. The injunction issued by the Court was to bar Andrx from producing further product, while the present damages claim relates to Andrx's commercial manufacture ***prior to*** the injunction. Specifically, Astra was damaged by Andrx's unauthorized commercial manufacturing of the patented product, and, as recognized by the Court, is entitled to a reasonable royalty for that infringing conduct: "Astra's damages claim is not futile because the patent statute sets the minimum quantum of damages as no less 'than a reasonable royalty for the use made of the invention by the infringer.'" (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 16 (quoting 35 U.S.C. § 284)). Astra has not yet been compensated for this trespass on its property rights. For this reason alone, Andrx's argument fails.

[13] Astra acknowledges that the 2010 Order and Opinion left open the question of whether Andrx's manufacture falls within the safe harbor provision. That, however, is not the issue before the Court. Andrx expressly admitted for the purposes of this motion that its manufacture falls outside of the § 271(e)(1) safe harbor. (Andrx's Opening Brief, Dkt. 83, p. 12, n. 6). And as shown in the Factual Background section, Andrx's executives admitted to the large scale commercial nature of Andrx's manufacture.

While Andrx characterizes its argument as "Double Recovery," it previously addressed this same issue in its opposition to Astra's motion to supplement its complaint. For example Andrx previously and unsuccessfully argued that "Astra's motion to supplement the complaints in an effort to ***get more relief*** from its first and second claim is ***barred by the fact that this court has issued judgment….***" (Ex. 7, Andrx's Opp. to Motion to Supplement, Dkt. 29, p 15 (emphasis added)). The reference to "an effort to get more relief" is just the previous way Andrx referred to its re-styled "double recovery" argument. For this reason, Andrx incorrectly argues that "double recovery" was not previously raised or decided by the Court. (Andrx's Opening Brief, Dkt. 83, p. 19). Similarly, the reference to "issued judgments" is just another way of arguing that the final judgment bars further relief and that res judicata should apply. Andrx also argued that Astra's damages claims were barred by res judicata elsewhere. (Ex. 7, Andrx's Opp. to Motion to Supplement, Dkt. 29, pp. 26-29).

The Court already twice considered and rejected these previously presented arguments. (e.g. Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 7-9 (addressing final judgment), pp. 11-12 (addressing the availability of both injunction and damages under § 271(e)(4)), p. 13 (addressing res judicata); Ex. 6, Order (April 5, 2010), Dkt. 40, p. 2). As just one example, the Court ruled that damages relief was available in addition to the previously entered judgment:

> Damages relief was not an issue at trial or one ready for resolution in October 2002, and it is therefore not precluded by the October 30, 2002 judgment. While the judgment precludes relitigation of infringement liability, it does not preclude the possibility of additional remedies for that infringement.

(Id. at 8-9). Andrx's summary judgment motion reargues issues previously considered and rejected by the Court. As explained in Section I(C), the law of the case doctrine should prevent

Andrx from re-opening these already decided issues, and should prevent Andrx from making arguments that could have been raised in response to the motion to supplement.

The cases cited by Andrx in its third bite at the apple (its present motion) are factually different from this case. Andrx quotes *Creek* (7th Cir.), where the court stated, "you cannot split a claim into a request for damages and a request for injunction and litigate each in a separate suit." (Andrx's Opening Brief, Dkt. 83, p. 17 (citing *Creek v. Village of Westhaven*, 80 F.3d 186, 190 (7th Cir. 1996))). But Astra is not litigating a separate suit – Astra is presenting its damages case in the same suit (a single complaint that was supplemented).[14] (*See* Ex. 1, Order & Opinion (Feb. 2, 2010), Dkt. 35, p. 1; Ex. 8-9, Second Supplemental Complaints, Dkt. 36).

Additionally, the court in *Creek* goes on to state, "[b]ut that is provided that you can obtain both forms of relief in one suit. If, when the claim arises, the amount of damages cannot be quantified, then you can delay bringing your suit for damages until they can be quantified." *Creek*, 80 F.3d at 190. In other words, the *Creek* court recognized that the plaintiff was entitled to bring a new suit even if the conduct complained of was the same conduct complained of in the first suit, since he could not estimate his full damages at the time of the original suit. *Id.* Similarly, in the present case, at the time of the original trial Astra was unable to quantify the amount of damages. Moreover, as previously addressed by this Court, the lack of information was due to Andrx's decision to withhold discovery on the commercial batches at that time. (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 2 (showing it was Andrx's decision), pp. 8-9 (showing damages issue was not yet ready for resolution).

[14] *Clark v. Redeker*, 406 F.2d 883 (8th Cir. 1969), *Fall Stamping & Welding Co. v. Int'l Union, United Auto. Workers, Aerospace & Agric. Implement Workers of Am.*, 744 F.2d 521 (6th Cir. 1984), *Lambert v. Conrad*, 536 F.2d 1183 (7th Cir. 1976), and *Mirin v. Nevada*, 547 F.2d 91 (9th Cir. 1976), cited by Andrx, all involve plaintiffs who brought claims for damages as part of a ***separate suit*** after a previous suit for injunctive relief on the same cause of action and as such are factually distinguishable.

Estate of Young is also distinguishable. *Estate of Young v. Williams*, 810 F.2d 363 (2d Cir. 1987). In that case, the plaintiff filed a suit seeking an injunction and then 6 months later filed a separate suit seeking damages for the same event that occurred prior to, and was the reason for, the original complaint. *Id.* at 364. A final judgment was entered in the first suit prior to the damages judgment in the second suit, and the appellate court reversed the damages judgment on grounds of res judicata. *Id.* Again, unlike the facts presented in *Estate of Young*, the events underlying Astra's damages claim did not occur until after the original complaint was filed (and as discussed above, could not be reasonably quantified and was not ready for resolution at the first trial). (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, p. 2, 8-9).

For this reason, Andrx's reference to the lack of a damages claim in the originally filed complaints (Andrx's Opening Brief, Dkt. 83, p. 2) is a red herring. This issue was fully addressed in the Court's 2010 Opinion. (Ex. 1, Opinion (Feb. 2, 2010), Dkt. 35, pp. 7-9).

Andrx also relies on *Forster* for the proposition that Astra is not entitled to both an injunction and damages. (Andrx's Opening Brief, Dkt. 83, p. 19, n. 8). First, the Court has already addressed and rejected this argument, finding that both injunction and damages are available for infringement under § 271(e)(2). (Ex. 1, Opinion & Order (Feb. 2, 2010), Dkt. 35, pp. 11-12). In *Forster*, the defendant breached a contract by failing to remove a swim dock. *Forster v. Boss*, 97 F.3d 1127, 1128-29. The plaintiffs were awarded both compensatory damages for the breach of contract, and also an injunction ordering the defendants to remove the swim dock. *Id.* The court found that either the compensatory damages or the injunction alone made the plaintiffs whole, and thus ruled that the plaintiffs would need to choose one or the other. *Id.* at 1129-30. As discussed above, while the injunction issued in this case protects Astra

against future infringing conduct, Astra has not yet been compensated for Andrx's past infringing acts that occurred prior to the injunction.

CONCLUSION

For the foregoing reasons, Andrx's motion for summary judgment on damages should be denied in full.

Dated: March 29, 2013

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CERTIFICATE OF SERVICE

I hereby state that on March 29, 2013, a true and correct copy of the foregoing **ASTRA AKTIEBOLAG'S OPPOSITION TO ANDRX PHARMACEUTICAL'S MOTION FOR SUMMARY JUDGMENT ON DAMAGES**, the **DECLARATION OF SURAJ K. BALUSU IN SUPPORT OF ASTRA AKTIEBOLAG'S OPPOSITION TO ANDRX PHARMACEUTICAL'S MOTION FOR SUMMARY JUDGMENT ON DAMAGES AND ACCOMPANYING EXHIBITS**, and **ASTRA AKTIEBOLAG'S RESPONSE TO ANDRX PHARMACEUTICALS, INC.'S STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT ON DAMAGES**, were served upon counsel of record by operation of the Court's ECF System, and were served by e-mail and by Federal Express upon the following counsel of record, as indicated below.

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